#### November 24, 2018

### Project Narrative Arizona Isotopes Science Research Corp. In Support of a Use Permit Application

#### **<u>1- Reason for the Use Permit Application</u>**

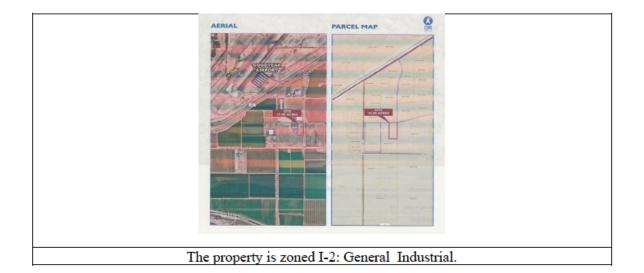
The following discussion provides the background necessary for understanding the reason for the application for a use permit.

The Arizona Isotopes Science Research Corp. ("AZI") is proposing to construct a state-of-the-art isotope production and research facility in Goodyear, Arizona. Isotope production will meet the current and growing need for medically-applied chemicals important to cardiac diagnoses and other diseases. Research is expected to be conducted in conjunction with Arizona's major universities. Similar isotope production facilities have been licensed and operated safely in Arizona for many years. This facility will employ approximately thirty highly skilled, well-paid specialists who, unlike those at distribution centers, will not be replaceable by robots in the coming years.

The proposed facility site is approximately 5 acres located just east of 14535 W. La Estrella. It is zoned I-2: General Industrial. The site is in an area that is modestly developed. Two small office building/warehouse units, one modest drywall production facility, and a Fresh Del Monte Produce Company facility that distributes fresh fruits and vegetables are within 500 feet of the site. Much of the rest of the immediate surrounding area is open land.

AZI believes that the proposed use is compatible with the foreseeable and expected development and uses permitted in the area.

- AZI's building will contain the manufacturing facility, offices, and research laboratories. These uses are all consistent with the I-2 zoning as described in Goodyear's Zoning Ordinance at Article 3: Zoning Districts, Section 3-4-2, A: Principal Permitted Uses.
- The City of Goodyear has encouraged technology oriented companies to locate in the City. Just recently, Microsoft announced that it purchased a large tract of open land directly to the east of this site. The location near the Goodyear-Phoenix Airport can be expected to attract businesses that need to rely on the availability of air transport.
- The Arizona Bureau of Radiation Control ("BRC") will review the license application for compliance with its health and safety requirements, review construction, and inspect operation of the facility. These activities provide a high level of confidence that the facility can be operated consistent with the public health and safety.



AZI plans to manufacture isotopes that are in short supply and sorely needed by the medical community to improve the diagnoses of several diseases, especially heart disease. Initially, AZI will produce Strontium-82 ("Sr-82") that decays into another radioactive element, Rubidium-82 ("Rb-82"). Physicians consider Sr-82/Rb-82 to be the "gold standard" for cardiac perfusion studies. The Los Alamos National Laboratory reported<sup>1</sup> that more than 30,000 patients/month in the United States benefit from this potentially life-saving tool. By injecting Rb-82 into the patient's blood stream, physicians can obtain the sharpest possible image of blood flow and cardiac function to view abnormalities resulting from disease.

Currently, AZI intends to produce only Strontium-82. AZI expects that it will take several months to establish a smooth production process so no other isotope would be produced for some time. AZI has not determined what other isotopes, if any, it may produce in the future. Therefore, it is premature to speculate about any additional materials that may be on site and the length of time that they may be there. Any amended license will have to comply with the BRC's regulations which will ensure that the public's health and safety will be protected and maintained.

When AZI proposes to produce other isotopes in the future, the BRC will have to amend AZI's license to include the production of the other radioactive materials. The BRC's review would take into account the cumulative impacts that would result from the production of additional isotopes. AZI hereby commits to informing the City of Goodyear of any proposed license application for other radioactive materials as soon as AZI applies for any such license. Any amended license will have to comply with the BRC's regulations which will ensure that the public's health and safety will be protected and maintained.

AZI will become the second and largest domestic commercial supplier of Sr-82. Prior to 2016, there were no commercial suppliers. Hospitals and clinics in the United States had to rely on foreign imports for their needs, imports that did not fully fill those needs. Thus, AZI's facility will serve the national interest in providing the best health care for Americans.

The heart of the facility is a machine called a cyclotron. The cyclotron that will be installed by AZI is a Cyclone 70 manufactured by Ion Beam Applications, S.A. The same kind of cyclotron made by the same manufacturer has been operating safely in Nantes, France, and in an industrial park in Noblesville, Indiana, a suburb of Indianapolis.

The Cyclone 70 is so named because it produces particles with energy of 70 million electron volts ("MeV"). This cyclotron is the product of years of research resulting in a design that is compact and able to achieve the energy needed to produce Sr-82. This makes it far more efficient than the older, much larger and higher energy machines used at U.S. National Laboratories to produce Sr-82.

The cyclotron creates a beam of the subatomic particle "proton" to strike a target composed of a very thin layer of the element rubidium that is electro-deposited onto water-cooled copper disks the size of an old-fashioned pocket watch. This proton beam converts some of the rubidium into Sr-82, which is radioactive. Sr-82 has a half-life of 25.34 days.

Several aspects of the facility show that it will not be materially detrimental to persons residing or working in the vicinity adjacent to the property, the neighborhood, or the public welfare.

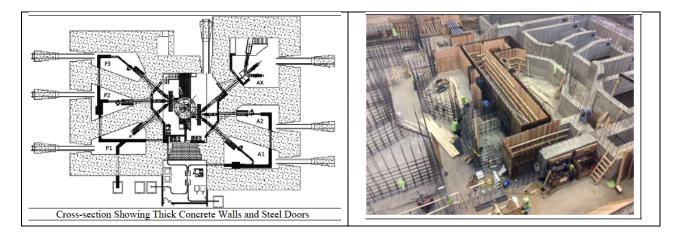
• The cyclotron will be encased in a vault constructed of concrete walls that are expected to be approximately ten feet thick with the final thickness determined by the BRC's regulatory requirements. The doors into the vault will be the same thickness and are made of steel and concrete. The doors are plugs that ride on rails. They slide back to be opened and slide forward to be closed, as shown on the cross-section diagram below. They cannot be opened while the cyclotron operates. The vault's design ensures that no radiation can escape. The design will be reviewed and approved by Arizona's Bureau of Radiation Control ("BRC") before the facility can be licensed by the State of Arizona. BRC regulatory oversight will continue during facility operation to ensure the safety of workers and the public.



The Cyclotron Vault



The Cyclotron in the Vault



- The targets are contained in specially designed rooms with very thick concrete walls, and thick steel and concrete doors that cannot open when the proton beam is on. The targets are handled and removed remotely, packaged, and shipped offsite by common carrier in accordance with U.S. Department of Transportation ("DOT") regulations.
- About six (6) grams of Sr-82 will be produced during each five-day run of the cyclotron. The material will be shipped offsite as quickly as possible after the end of the production run because half of it decays away in 25 days. Accordingly, no product is expected to be stored at the facility for any length of time. After 280 days the material is no longer considered radioactive.
- No more than a pound of rubidium is expected to be stored on the site. One pound of rubidium has a volume of about one-hundredth of a cubic foot. It would fit in a few matchbox-sized containers. Because the license issued by the Arizona Bureau of Radiation Control ("BRC") will contain limits on the amount of radioactive material that may be on site at any time and those license condition limits will be based on compliance with the BRC's safety regulations, the amount of radioactive material on site will satisfy all safety requirements.
- Assurance that AZI will not exceed the amount of radioactive material allowed to be on site at any time is provided by AZI's commitment to public health and safety and is reinforced by the BRC's ongoing oversight and inspection of AZI's facility. Specifically, because AZI's product for sale has a short half-life, AZI has a strong economic motive to ship material as soon as it is ready for commercial use.
- The low-level radioactive waste will be intrinsically limited by the nature of AZI's production process. Experience at the Noblesville, Indiana facility shows that after almost twenty months of operation a volume of about 14 gallons of mainly solid low-level radioactive waste has been created. It is stored safely in a sealed, concrete room, with controlled entry. When the low-level waste fills a 55-gallon drum, it will be sent offsite for disposal. AZI hereby commits to shipping low-level waste to a licensed disposal facility as soon as it accumulates the minimum amount acceptable for disposal by that facility.

• AZI currently intends to limit the total amount on site at any time to the smallest quantity necessary to maintain an uninterrupted production process. At full production level, about a pound a year will be needed. As rubidium is used up it will be replaced by the amounts necessary to maintain uninterrupted production but is not expected to exceed one pound. AZI intends to limit its on-site stock to one pound as a maximum. A second cyclotron likely will be used to generate other isotopes using different elements as inputs, but if it is used to also generate Sr-82, AZI expects to replace the used up rubidium on a more frequent basis rather than storing more than a pound on site. However, to avoid possible interference with production, AZI believes that the use permit should include the flexibility for AZI to store more than one pound of rubidium if two cyclotrons are used to produce Sr-82. AZI will work with the City of Goodyear to adopt any additional controls that may be determined to be appropriate.

Currently, one cyclotron will be constructed on the site. AZI intends to construct a second cyclotron provided that it would be commercially viable. Although AZI believes that a second cyclotron would be economically supportable, only time will tell about the validity of that prediction.

The operation of a second cyclotron will not be materially detrimental to persons residing or working in the vicinity adjacent to the property, to the neighborhood, or the public welfare.

- If AZI determines to construct and operate a second cyclotron it would be subjected to the BRC's regulatory review, approval, and oversight during operation.
- The BRC's review would take into account the cumulative impacts that would result from the operation of two cyclotrons on the site and would impose license conditions that would ensure the public health and safety would not be adversely impacted by the presence of two cyclotrons.
- The waste generated by a second machine producing the same isotope would double the total amount of waste produced. As for the production of a different isotope, AZI is committed to coordinating this activity with the City of Goodyear before production begins, whether it is on either the first or second cyclotron.

The construction of a second cyclotron also will be reasonably compatible with uses permitted in the surrounding area.

• The exterior building will be constructed to contain two cyclotrons. Thus, the addition of the second cyclotron will not be noticeable externally. The exterior building containing the vault and the target areas is neither required nor expected to provide a barrier to radiation. The vault and target areas are designed to absorb any radiation before it reaches the outer surfaces of the vault or the target areas. The exterior building may be either concrete or steel frame with panels as approved by the City of Goodyear.

• The second cyclotron will enable AZI to also conduct research, another permitted use for this zoning. Such expansion of the facility to employee more workers and conduct related, permitted activities is consistent with the City of Goodyear's long-term goals.

With this background in mind, we now turn to the reasons for this application for a use permit.

#### Strontium-82

Article 2 of Goodyear's Zoning Ordinance defines Hazardous Materials/Explosives as:

Any substance characterized as flammable solids, corrosive liquids, <u>radioactive materials</u>, oxidizing materials highly toxic materials, poisonous gases, reactive materials, unstable materials, hypergolic materials and pyrophoric materials and any substance or mixture of substances which is an irritant, a strong sensitizer or which generates pressure through exposure to heat, decomposition or other means. (emphasis supplied)

Section 3-4-2 C: Use Permit Uses, #6 provides that the following uses require a use permit.

hazardous processes or explosive storage, including those materials or products such as manganese or fuel oil and similar materials which represent fire hazards will be used only upon Fire Chief approval.

Sr-82 is radioactive. The City of Goodyear relied on Article 2 above to consider Sr-82 to be a hazardous material and, as a result, has applied Section 3-4-2 C to require AZI to obtain a use permit to ensure the protection of public health and safety.

AZI believes that the presence of Strontium-82 will not be materially detrimental to persons residing or working in the vicinity adjacent to the property, to the neighborhood, or to the public welfare.

- The Arizona Bureau of Radiation's ("BRC") regulations, license requirements, licensing process, and continuing post-licensing oversight are specifically designed to ensure that AZI's creation and distribution of radioactive materials include procedures that protect public health and safety.
- Note that the City of Phoenix determined that a proposed cyclotron met zoning requirements based its containment of all operations in the building and its compliance with all regulatory requirements.

### <u>Rubidium</u>

Rubidium is the element that the cyclotron converts into Strontium-82. The amount of rubidium that AZI expects to store on site will be limited to the smallest quantity necessary for an uninterrupted production process, that is, no more than one pound when only one cyclotron is operated to produce Sr-82. If a second cyclotron also produce Sr-82, the amount stored on site may be increased but it is expected that instead of storing more material the replacement of used up materials will be done more frequently. To appreciate how small a volume is taken up by one pound of rubidium, consider that one pound of rubidium has a volume of about one-hundredth of

a cubic foot. It would fit in a few matchbox-sized containers. Should AZI propose to store more rubidium in the future, AZI will work with the City of Goodyear to adopt any additional controls that may be determined to be appropriate.

AZI's on-site storage of rubidium will not be materially detrimental to persons residing or working in the vicinity adjacent to the property, to the neighborhood, or to the public welfare for the following reasons.

- Because rubidium is pyrophoric (subject to spontaneous combustion), it is subject to Article 2 and Section 3-4-2 C above, and will be handled accordingly.
- Rubidium will be stored within a controlled atmosphere of inert gas in a sealed container maintained at a controlled temperature and monitored with alarms to ensure its stability.
- The volume of rubidium stored is small (able to fit within a few match-box sized containers that together could fit into a space the size of a shoe box).
- Automatically released fire-suppressant gasses will be available in the rare event of combustion.
- All handling of rubidium will be conducted in sealed areas so that no combustion products will escape from the facility.
- Details about these protective measures will be provided to the Fire Chief for review and approval. (NOTE: The initial isotope of rubidium that is irradiated by the proton beam and transmuted in Sr-82 is not radioactive. Sr-82 decays into Rb-82 which is radioactive and is used for cardiac diagnoses.)

<u>Emissions Outside the Site Perimeter</u> Section 3-4-2 D: Development Regulations, Paragraph #3 provides that;

No use is permitted which will emit any offensive odor, dust, noxious gas, noise vibration, smoke, heat or glare beyond the boundaries of the lot on which such use is conducted.

AZI's facility will produce very small amounts of certain atmospheric gases, Argon, Nitrogen, Oxygen, and Carbon that have become radioactive through neutron activation. These gases have very short half-lives. The air in AZI's facility will be processed to remove these low levels of activated gases before air is released from the facility.

The following isotopes of atmospheric gases will be created during cyclotron operation:

Element	Half-Life
Carbon 11	20.3 minutes
Nitrogen 13	9.97 minutes
Oxygen 15	122.2 seconds
Argon 41	109.61 minutes

Radiation protection practice considers that a radioactive material is no longer considered radioactive after 10 half-lives because less than one-thousandth of the original amount of radioactive material remains by the end of that period. At Noblesville, a passive system is used to ensure that radiation exposures to the public from the release of these isotopes is below regulatory limits. Noblesville uses a vent in the form of a pipe that is long enough so that the travel times of the gaseous isotopes to the outside vent is approximately ten half-lives.

AZI will take the following actions to ensure that these releases will be negligible so as not to be materially detrimental to persons residing or working in the vicinity adjacent to the property, to the neighborhood, or to the public welfare.

- AZI intends to use an active filtration system that will somewhat delay the release of these isotopes into the atmosphere and will propel them high enough to be diluted so that any inhalation of them meets regulatory limits with a margin of safety. AZI considers a negligible level of exposure to be a fraction of the regulatory limit. The exact levels will be determined after the detailed design of the exhaust system is completed and reviewed and approved by the BRC.
- The shutdown mechanism in the exhaust stack will meet the BRC's regulatory requirements for ensuring that no member of the public could receive a dose that exceeds regulatory limits.

### 2 – How the application may impact adjacent properties

This facility will have only the usual impacts that any building of this size and work force would have on adjacent properties. From the outside, the building will be designed to look like any other typical industrial facility in the area. No radioactivity-related impacts could be experienced by adjacent properties. The facilities processes and work force of approximately 30 individuals will not noticeably impact public services or roads.

As described above, no radiation can escape from the heavy shielding provided by the thick concrete walls and thick steel and concrete doors that comprise the cyclotron vault and the target areas. The comprehensive licensing and regulatory processes conducted by the BRC, together with the effectiveness of the shielding and safety procedures practiced by the AZI staff, will prevent escape of radiation from the facility.

The regulatory processes conducted by the BRC include: (1) a detailed technical review of the building plans, operating procedures, and operator training before and during construction; (2) inspections of construction activities; and (3) inspections during operation. The frequencies of BRC inspections will vary depending on inspection experience; inspection frequency and intensity will increase if there are compliance issues at the facility.

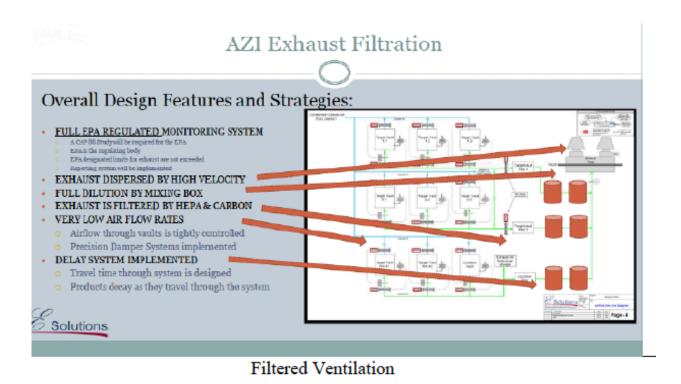
The accident and environmental analyses of all facilities involved with radiation and radioactive materials are based on determining the possible adverse consequences arising from events that have a plausible likelihood of occurrence. Worst-case scenarios that are implausible are not evaluated. Some employees' failures to follow safety procedures are

plausible and will be evaluated in light of the automatic safety features in the plant, such as interlocks which prevent the opening of the door to a target vault while the cyclotron is operating. The facility will be designed and operated so that the uncontrolled release of either radioactivity or radioactive materials to the public as a result of a failure to follow procedures will be implausible. However, because failures to follow procedures may be found to result in the potential for workers to be overexposed to radiation, strict procedural adherence will be rigorously enforced at the facility.

Only a very small volume of radioactive Sr-82 product is created during each cyclotron run and at the conclusion of the run, it is promptly shipped off-site in accordance with U.S. DOT safety standards. Actions for handling the radioactive material and preparing it for shipment are conducted in secure locations that prevent the release of any radioactive material. In the very highly unlikely event of a fire in the enclosure containing the radioactive material, combustion products would not escape from the facility because of the heavy steel and concrete containment and atmospheric control that will prevent the escape of any contaminants. We are not aware of any fire having occurred in any comparable facilities.

The small quantities of short half-lived activated atmospheric gases will not be permitted to escape into the environment. Air in the facility will be passed through filters mounted in chimneys on top of the facility. Fans inside the chimneys will propel the filtered air high into the atmosphere where any remaining activated gases are diluted so that any exposure to persons at ground level is negligible and well within regulatory limits.

The BRC regulates this process to ensure that no hazard is created. Any exposure to airborne radioactive gases would be well-below regulatory limits. If for any reason a filter should fail, a monitor in the stack would cause the stack to close automatically, thus preventing any unfiltered air from escaping. AZI believes that its use of this method, the BRC's regulation and oversight, and AZI's equipment design will enable Goodyear to rely on these factors as a firm basis to find that the facility will not emit any noxious gas beyond the boundaries of the lot.



Finally, the very small amounts of low-level radioactive waste temporarily stored on-site awaiting disposal presents no impact on adjacent properties. The waste is stored in a concrete shielded room subject to stringent access control. No credible fire could disperse the waste into the adjacent properties. These low-level wastes will be periodically shipped out to a licensed waste disposal facility.

### **3.City policies supporting the proposed application**

Objectives in Goodyear 2025, the City of Goodyear's General Plan will be advanced by the presence of this facility in Goodyear. Objective ED-1-1 will be met because the development of this facility will create jobs that offer high wages and are not replaceable by robots. Goal ED-4, creation of a community that is a technology leader in health care will be met because the facility will produce the isotope needed for the most accurate diagnoses of heart conditions. Further, AZI's expected collaborative research with Arizona's universities will strengthen Goodyear's position as a leader in technological development. Objective ED-4-1 will be met because location of the facility in Goodyear will promote the development of technology and Goodyear as a technology leader. Goal ED-2 will be met because AZI will nurture locally based employment through the creation of new jobs.

**4-How the proposed use will not be materially detrimental to persons residing or working in the vicinity adjacent to the property, to the neighborhood, or to the public welfare** For the reasons described above, this facility will not have any detrimental impacts on persons residing or working in the vicinity adjacent to the property, to the neighborhood, or to the public welfare.

# 5-How the proposed use is reasonably compatible with uses permitted in the surrounding area; mitigation of potential impacts on surrounding properties such as, but not limited to, noise, lighting, odor, or placement of trash receptacles

Uses permitted in the surrounding area are few and limited to the types of activities consistent with the I-2 zoning. Because the facility will be designed, regulated, and operated to eliminate any impacts on the external environment that are different from the usual impacts from a manufacturing and research facility that satisfies I-2 zoning, this facility is compatible with existing facilities. Moreover, this facility will not create any unusual amounts of noise, lighting, odor, or trash needing receptacles. AZI visible activity level will be far below that of the neighboring Del Monte processing plant.

# 6-Assurance of adequate parking, as well as ingress and egress so to not increase traffic congestion

The adequacy of parking and access is clearly shown on the accompanying plans. The facility will have a total work force of approximately thirty individual spread over three shifts. No significant number of visitors is expected.

Product shipments will be made once every week. Strontium-82 will be shipped by common carrier, usually either UPS or FedEx. No other types of special purpose vehicles are expected on regular basis. Thus, this facility will not contribute to traffic congestion.

The level of activity will increase if there is a second cyclotron but the extent and nature of those activities is not clear. AZI expects eventually to initiate a scientific research and development program for either creating new isotopes with medical uses. Such activities would be different in kind from production activities and their relative levels might be hard to compare. However, these additional activities are not likely to significantly increase worker-commuter or other kinds of traffic.

## **7-Hours of operation**

The facility will operate for twenty-four hours a day for five days at a time. The other two days of operations will be limited as the plant undergoes maintenance.

# **<u>8-Maintenance of a positive appearance, with appropriate screening, landscaping, and buffering to preserve reasonable use and enjoyment of adjacent properties</u>**

The exterior building and landscaping will meet all City of Goodyear design requirements. The building will be appropriately set back on the site. From the outside, there will be no indication of the activities inside the building and no environmental impacts. Aside from seeing the building, the limited adjacent properties will not experience any impact on their use and enjoyment.

<sup>1</sup> <u>https://permalink.lanl.gov/object/tr?what=info:lanl-repo/lareport/LA-UR-13-25835</u>.